acid), wherein the numbering of the amino acid residues is based upon the numbering of the amino acid residues in the RSV wild-type strain RSV 2B (SEQ ID NO:2).

Remarks

The Examiner has requested that Applicants provide the status of all parent priority applications. Applicants have done so by amending page 1 of the specification to recite the requested information.

In response to the Examiner's statement that the declaration is defective, Applicants enclose herewith a new Declaration and Power of Attorney in compliance with 37 C.F.R. 1.67(a). Note that there are only three named inventors of this application.

The Examiner has rejected Claim 2 under 35 U.S.C. 112, second paragraph, as allegedly being indefinite, for describing mutations by an amino acid number without providing which viral strain numbering system is used. In response, as a preliminary matter, Applicants are amending Claim 1 to incorporate the limitations of Claim 2 to more clearly define their invention. Claim 2 is being cancelled. (Claim 4 is also being cancelled; the incorporation of the limitations of Claim 2 into Claim 1 renders Claim 4

redundant of Claim 3.) Therefore, the Examiner's rejection now applies to amended Claim 1.

In response, Applicants are further amending Claim 1 to recite that "the numbering of the amino acid residues is based upon the numbering of the amino acid residues in the RSV wild-type strain RSV 2B (SEQ ID NO:2)". Support for this amendment is provided by the specification at page 27, lines 19-22, page 33, lines 1-3 and 18-21, and SEQ ID NO:2. Applicants respectfully submit that, as amended, Claim 1 satisfies 35 U.S.C. 112, second paragraph.

Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The first attached page is captioned "Version With Markings To Show Changes Made".

The Examiner has rejected Claims 1 and 2 under 35 U.S.C. 112, first paragraph, as allegedly not being enabled by the specification for an attenuated virus by making a single mutation in the RNA polymerase gene. The Examiner concedes that the specification is enabling for attenuated viral mutants that have multiple mutations. As discussed above, Claim 1 now incorporates the limitations of Claim 2.

Applicants respectfully submit that a close reading of the specification fully supports claims to isolated, recombinantly-generated, attenuated, RSV subgroup B having at least one defined attenuating mutation in the RNA polymerase (L) gene. This is particularly true with regard to the mutations resulting in changes in amino acid residues 451 and 2050.

The specification recites at page 55, lines 2-16:

> "In 2B33F, a mutation at nucleotide position 9853 (A → G) leading to a coding change in L protein at amino acid 451 (Lys → Arg) is clearly associated with the *ts* and attenuation phenotypes. Reversion at this site alone in the 2B33F TS(+) 5a strain is responsible for complete restoration of growth at 39°C (Table 23) and partial reversion in attenuation in animals. This association of *ts* was also supported by partial sequence analyses of six additional "full *ts* revertants" (designated 4a, 3b, pp2, 3A, 5a, 5A) isolated from cell culture and from chimps, in which only the nucleotide 9853 mutation reverted (Tables 24-26) (note that one AGM (African Green Monkey) isolate which reverted at 9853 only partially reverted in *ts* phenotype)."

Thus, the attenuating nature of the mutation at amino acid residue 451 has been demonstrated.

The specification further recites at page 55, lines 22-33:

> "In 2B20L, a mutation at base 14,649 (A → G) leading to a coding change in the L protein (amino

> acid position 2,050, Asn → Asp) appears to be associated with the *ts* and attenuation phenotypes. This aspartic acid at the amino acid 2050 invariably reverts back (Asp → Asn) in TS(+) revertants or changes to a different amino acid (Asp → Val) by nucleotide substitution at position 14,650 (A → T) (Tables 22, 25). The above observation is based on complete sequence analysis on the TS(+) revertant R1 and partial sequence of several additional TS(+) revertants (R2, R4A, R7A, R8A) at selected regions (Table 25)."

Thus, the attenuating nature of the mutation at amino acid residue 2050 has been demonstrated.

The sequence comparisons reported in Tables 21 and 22, together with the *in vitro* and *in vivo* experiments and the sequence analyses of Tables 23-26, further support the importance of each of the mutations claimed by Applicants.

In addition, the specification further provides details as to how a person skilled in the art of recombinant negative-stranded RNA viruses would introduce one or more claimed mutations in the polymerase (page 20, lines 3-33), rescue a claimed virus containing one or more listed mutations in the polymerase (page 22, line 11, through page 23, line 30), test the virus to confirm the presence of the desired attenuated phenotype (page 23, lines 31 through 34),

and then conduct challenge experiments with an appropriate animal model (page 23, line 35 through page 24, line 17).

The Examiner's reliance on Juhasz et al. (Journal of Virology) is not appropriate. Juhasz et al. focused on identifying mutations in the L gene that resulted in the desired ts phenotype of the RSV subgroup A. In contrast, Applicants describe and claim mutations in the L gene which confer attenuation to RSV subgroup B strains.

Thus, for the reasons stated above, Applicants respectfully submit that the cited portions of the specification enable a person of ordinary skill in this art to practice the claimed invention without undue experimentation, such that the specification enables the claims under U.S.C. 112, first paragraph.

The Examiner has rejected all the claims under 35 U.S.C. 102(e) as allegedly being anticipated by Randolph et al. (U.S. Pat. No. 5,932,222) ("Randolph U.S.").

Applicants were the first to analyze the sequence of RSV subgroup B wild-type and vaccine strains with respect to the polymerase gene. Without both a knowledge of the sequences themselves and an analysis of the differences

between the sequences, it is impossible to identify attenuating mutations in a vaccine strain.

Randolph U.S. discloses the existence of the 2B wild-type and the 2B33F and 2B20L vaccine strains. However, Randolph U.S. does not provide any sequence information about these strains.

Therefore, Randolph U.S. cannot teach a difference between a wild-type strain and a vaccine strain at one or more of amino acids 353, 451, 1229, 2029 and 2050 in the polymerase of RSV subgroup B, nor does Randolph U.S. teach that any of these mutations are attenuating. For these reasons, Randolph U.S. cannot anticipate Applicants' claims, because, according to the Court of Appeals for the Federal Circuit's decision in In re Bond, 15 USPQ2d 1566, 1567 (Fed. Cir. 1990):

> "For a prior art reference to anticipate in terms of 35 U.S.C. 102, every element of the claimed invention must be identically shown in a single reference."

The Examiner nonetheless contends that the depositing of various RSV subgroup B strains referred to in Randolph U.S. means that Randolph U.S. inherently possesses the sequences claimed by Applicants.

Applicants respectfully submit that this is an incorrect statement of the law. A distinction must be drawn between the physical characteristics of a product and its structure. In the case of a virus containing one or more attenuating mutations, the physical characteristics include the phenotype of the virus, such as attenuation, growth, immunogenicity. In contrast, the structure is its genotype, the specific nucleotide sequence which encodes a specific amino acid sequence.

The two cases cited by the Examiner are not relevant on this point. In re Best involved a patent application directed to a catalyst. Both the application and the cited prior art described the catalyst in terms of physical, not structural characteristics. In contrast to In re Best, here the prior art (Randolph U.S.) described the virus only in terms of physical characteristics, while this application describes the virus in terms of structural characteristics. In re Schreiber is even less relevant. That case involved a medical device, not a chemical or biological composition.

Far more relevant is the recent decision by the Court of Appeals for the Federal Circuit in Enzo Biochem

Inc. v. Gen-Probe Inc., 62 USPQ2d 1289 (Fed.Cir. 2002) (a copy of this decision is attached for reference). In Enzo, the Federal Circuit invalidated a patent on the ground of failure to meet the written description requirement of 35 U.S.C. 112, first paragraph.

The patent claimed "a composition of matter that is specific for *Neisseria gonorrhoeae* comprising at least one nucleotide sequence for which the ratio of the amount of said sequence which hybridizes to chromosomal DNA of *Neisseria gonorrhoeae* to the amount of said sequence which hybridizes to chromosomal DNA of *Neisseria meningitidis* is greater than about five".

The patentee in Enzo had deposited three strains of *Neisseria gonorrhoeae* with the ATCC, but did not provide any nucleotide or amino acid sequences for these or any other strains.

The Examiner is directed to the following relevant statements in Enzo:

> "We conclude that, in this case, the district court correctly determined that the specification failed to provide an adequate written description of th claimed compositions. The court correctly found that the claimed nucleotide sequence is d scribed only by its binding to *N. gonorrhoeae* in a preferential ratio of "greater than about five"

> with respect to *N. meningitidis*. While that description of the ability of the claimed probe to bind to *N. gonorrhoeae* may describe the probe's function, it does not describe the probe itself. (62 USPQ2d at 1292)
>
> "The [PTO Written Description] Guidelines do not provide that a nucleotide sequence may be defined only by its function. (62 USPQ2d at 1293)
>
> "An invention may be properly enabled even if some experimentation is required to practice it, provided that experimentation is not undue. However, to require the public to go to a public depository and perform experiments to identify an invention is not consistent with the statutory requirement to describe one's invention in the specification. (62 USPQ2d at 1294)
>
> "However, its mere possession of three nucleotide sequences that are within the scope of the claims does not provide sufficient distinguishing information about those sequences for purposes of satisfying § 112, ¶ 1. Enzo provided only vague details about the nucleotide sequences: how they were obtained (but not meaningfully identified) and their approximate lengths. '659 patent, col. 13, ll. 26-60; col. 26, l. 56 to col. 27, l. 20. That meager information does not allow one skilled in the art to visualize or recognize the identity of the claimed subject matter. (62 USPQ2d at 1295)
>
> "Even if Enzo's expert, Dr. Wetmur, were correct that one of skill in the art could routinely sequence the deposited material and so obtain a description of those deposits, that description is not in the patent. The written description requirement is not satisfied by what could have been disclosed, but was not." (62 USPQ2d at 1295)

The instant application exactly parallels the fact pattern in Enzo. The patentees in Enzo and Randolph U.S. each had

deposited biological materials with the ATCC. Neither disclosed any nucleotide or amino acid sequences regarding those deposited materials. The Federal Circuit in Enzo held that the deposited materials plus a recitation of their hybridization specificity did not provide an adequate written description of the structure, that is, the sequence of the materials.

By the same reasoning, it should be held here that Randolph U.S. also did not provide an adequate written description of the structure, that is, the sequence of the RSV B strains, by virtue of the deposited materials plus characterization of their phenotypic properties. Therefore, it is incorrect to state that Randolph U.S. inherently possessed the nucleotide sequences claimed in this application.

For the reasons stated above, the claims are not anticipated by Randolph U.S. Nor are these claims rendered obvious by Randolph U.S.

The Examiner has also rejected all the claims under 35 U.S.C. 102(b) as allegedly being anticipated by Randolph t al. (EP 0 567 100 A1) ("Randolph EP"). Randolph EP claims the same priority as Randolph U.S. and has

essentially the same disclosure. Therefore, Randolph EP cannot anticipate or render the claims obvious, for all the reasons set forth above with respect to Randolph U.S.

In conclusion, the Applicants respectfully submit that the claims as amended comply with 35 U.S.C. 112, first and second paragraphs, and are not anticipated by the references cited by the Examiner. Reconsideration of the claims is requested and allowance is solicited.

Respectfully submitted,

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Version With Markings To Show Changes Made

1. (Amended) An isolated, recombinantly-generated, attenuated, human respiratory syncytial virus (RSV) subgroup B having at least one attenuating mutation in the RNA polymerase gene, wherein the at least one attenuating mutation in the RNA polymerase gene is selected from the group consisting of nucleotide changes which produce changes in an amino acid selected from the group consisting of residues 353 (arginine → lysine), 451 (lysine → arginine), 1229 (aspartic acid → asparagine), 2029 (threonine → isoleucine) and 2050 (asparagine → aspartic acid), wherein the numbering of the amino acid residues is based upon the numbering of the amino acid residues in the RSV wild-type strain RSV 2B (SEQ ID NO:2).

2. (Cancelled.)

3. A vaccine comprising an isolated, recombinantly-generated, attenuated RSV subgroup B according to Claim 1 and a physiologically acceptable carrier.

4. (Cancelled.)

5. (Cancelled.)

6. (Cancelled.)

7. (Cancelled.)

8. (Cancelled.)

9. (Cancelled.)

10. (Cancelled.)

11. (Cancelled.)

Enzo Biochem Inc. v. Gen-Probe Inc.

U.S. Court of Appeals
Federal Circuit
No. 01-1230
Decided April 2, 2002

PATENTS

[1] Patentability/Validity — Specification — Written description (§ 115.1103)

Claims for nucleic acid probes that are described solely in terms of their ability to selectively hybridize to genetic material of bacteria that cause gonorrhea do not satisfy written description requirement of 35 U.S.C. § 112, since such description may describe probes' function, but it does not describe probes themselves, and since hybridization is not distinctive "chemical property" of claimed nucleotide sequences; Manual of Patent Examining Procedure's guidelines for examination of patent applications under written description requirement do not provide that nucleotide sequence may be defined solely by its function, and in absence of sequence information for its hybridization site, nucleic acid described only by its ability to hybridize with another DNA fails to meet written description requirement.

[2] Patentability/Validity — Specification — Written description (§ 115.1103)

Claims for nucleic acid probes that are described solely in terms of their ability to selectively hybridize to genetic material of bacteria that cause gonorrhea do not satisfy written description requirement of 35 U.S.C. § 112, even though probes are described in same words in specification, since, if words of claim alone do not convey adequate description of invention, then repetition of same words in original specification will not satisfy written description requirement.

[3] Patentability/Validity — Specification — Written description (§ 115.1103)

Applicant's "possession" of claimed subject matter as of application date is not sufficient to satisfy written description requirement of 35 U.S.C. § 112 if invention is not adequately described in specification, since ensuring that applicant had possession of invention is merely one purpose of written description requirement, and is secondary to statutory mandate that specification contain written description of invention, and since that requirement is not met if, despite showing of possession, specification does not adequately describe claimed invention.

[4] Patentability/Validity — Specification — Written description (§ 115.1103)

Deposit of biological materials in public depository does not necessarily satisfy written description requirement of 35 U.S.C. § 112, since deposit requirement applies only to biological materials that are not readily reproducible from their written description, and accession number and deposit date add nothing to such description, since adequate written description of invention is necessary for proper examination of patent application, and on patent issues, description must be sufficient to aid in resolution of infringement issues, and since deposit therefore is not substitute for description of claimed invention in specification.

[5] Patentability/Validity — Date of invention — Reduction to practice (§ 115.0405)

Patentability/Validity — Specification — Written description (§ 115.1103)

Patent's description of invention's reduction to practice, unaccompanied by any meaningful, distinguishing characteristics of claimed nucleic acid probes, is insufficient to satisfy written description requirement of 35 U.S.C. § 112, since inventors could have provided description of claimed nucleotide sequences, since actual reduction to practice may demonstrate possession of embodiment of invention but it does not necessarily describe what invention is, and since, in context of present case, disclosure of manner in which invention was reduced to practice does not satisfy more fundamental written description requirement set forth in Section 112.

Particular patents — Chemical — Nucleic acid probes

4,900,659, Lo and Yang, nucleotide sequence composition and method for detection of Neisseria gonorrhoeae and method for screening for a nucleotide sequence that is specific for a genetically distinct group, summary judgment of invalidity affirmed.

Appeal from the U.S. District Court for the Southern District of New York, Hellerstein, J.

Action by Enzo Biochem Inc. against Gen-Probe Inc., Chugai Pharma U.S.A. Inc., Chugai Pharmaceutical Co. Ltd., Biomerieux Inc., Becton Dickinson and Co., and Biomerieux SA for patent infringement. Plaintiff appeals from summary judgment of patent invalidity. Affirmed; Dyk, J., dissenting in separate opinion.

Richard L. DeLucia, Charles A. Weiss, and Bradley S. Corsello, of Kenyon & Kenyon, New York, N.Y., for plaintiff-appellant.

William F. Lee and William G. McElwain, of Hale & Dorr, Boston, Mass., for defendants-appellees.

Robert J. Gunther Jr., Jeffrey A. Tochner, and Kurt M. Rogers, of Latham & Watkins, New York, for Chugai Pharma U.S.A. Inc. and Chugai Pharmaceutical Co. Ltd.

Daniel A. Boehnen and Joshua R. Rich, of McDonnell, Boehnen, Hulbert & Berghoff, Chicago, Ill., for Biomerieux Inc.

Donald R. Ware and Barbara A. Fiacco, of Foley, Hoag & Eliot, Boston, Mass., for Becton Dickinson and Co.

Before Lourie, Dyk, and Prost, circuit judges.

Lourie, J.

Enzo Biochem, Inc. appeals from the decision of the United States District Court for the Southern District of New York granting Gen-Probe Incorporated, Chugai Pharma U.S.A., Inc., Chugai Pharmaceutical Co., Ltd., Biomerieux, Inc., Biomerieux SA, and Becton Dickinson and Company's (collectively, "the defendants") motion for summary judgment that claims 1-6 of U.S. Patent 4,900,659 are invalid for failure to meet the written description requirement of 35 U.S.C. § 112, ¶ 1. *Enzo Biochem, Inc. v. Gen-Probe Inc.*, No. 99 Civ. 4548 (S.D.N.Y. Apr. 4, 2001) (final order). Because the district court did not err in its conclusion that there were no genuine issues of material fact and that the defendants were entitled to judgment as a matter of law, we affirm.

BACKGROUND

Enzo is the assignee of the '659 patent, which is directed to nucleic acid probes that selectively hybridize to the genetic material of the bacteria that cause gonorrhea, *Neisseria gonorrhoeae*. *N. gonorrhoeae* reportedly has between eighty and ninety-three percent homology with *Neisseria meningitidis*. '659 patent, col. 2, ll. 61-64. Such a high degree of homology has made detection of *N. gonorrhoeae* difficult, as any probe capable of detecting *N. gonorrhoeae* may also show a positive result when only *N. meningitidis* is present. Enzo recognized the need for a chromosomal DNA probe specific for *N. gonorrhoeae*, and it derived three such probes that preferentially hybridized to six common strains of *N. gonorrhoeae* over six common strains of *N. meningitidis*. *Id.* at col. 3, l. 49 to col. 4, l. 14; col. 4, ll. 45-50. The inventors believed that if the preferential hybridization ratio of *N. gonorrhoeae* to *N. meningitidis* were greater than about five to one, then the "discrete nucleotide sequence will hybridize to virtually all strains of *Neisseria gonorrhoeae* and to no strain of *Neisseria meningitidis*." *Id.* at col. 12, ll. 60-65. The three probes that the inventors actually derived had a selective hybridization ratio of greater than fifty. *Id.* at col. 13, ll. 9-15. Enzo deposited those probes in the form of a recombinant DNA molecule within an *E. coli* bacterial host at the American Type Culture Collection. *Id.* at col. 13, ll. 27-31.

Claim 1, in relevant part, is as follows:

> 1. A composition of matter that is specific for *Neisseria gonorrhoeae* comprising at least one nucleotide sequence *for which the ratio of the amount of said sequence which hybridizes to chromosomal DNA of Neisseria gonorrhoeae to the amount of said sequence which hybridizes to chromosomal DNA of Neisseria meningitidis is greater than about five*, said ratio being obtained by a method comprising the folllowing [sic] steps;

Id. at col. 27, ll. 29-36 (emphasis added). The method steps that follow are directed to obtaining the claimed ratio. *Id.* at col. 27, l. 37 to col. 28, l. 26. Claim 4 is directed to the deposited probes (referenced by their accession numbers) and variations thereof as follows:

> 4. The composition of claim 1 wherein said nucleotide sequences are selected from the group consisting of:
>
> a. the *Neisseria gonorroheae* [sic] DNA insert of ATCC 53409, ATCC 53410 and ATCC 53411, and discrete nucleotide subsequences thereof,
>
> b. mutated discrete nucleotide sequences of any of the foregoing inserts that are within said hybridization ratio and subsequences thereof; and
>
> c. mixtures thereof.

Id. at col. 28, ll. 31-39. Claim 6 is directed to a method of conducting a hybridization assay with the deposited probes and variations thereof. *Id.* at col. 28, ll. 47-56.

Enzo sued the defendants for infringement of the '659 patent, and the defendants moved for summary judgment that the claims were invalid for failure to meet the written description requirement of 35 U.S.C. § 112, ¶ 1. The district court, in oral remarks from the bench, granted that motion. Tr. of Hr'g at 42, *Enzo Biochem, Inc. v. Gen-Probe, Inc.*, No. 99-CV-4548 (S.D.N.Y. Jan. 24, 2001) ("*Enzo Hearing*"). It concluded that the claimed composition of matter was defined only by its biological activity or function, *viz.*, the ability to hybridize to *N. gonorrhoeae* in a ratio of better than about five with respect to *N. meningitidis*, which was insufficient to satisfy the § 112, ¶ 1 requirement set forth in this court's holdings in *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997), *Fiers v. Revel*, 984 F.2d 1164, 25 USPQ2d 1601 (Fed. Cir. 1993), and *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir. 1991). *Id.* at 28. The court rejected Enzo's argument that the reference in the specification to the deposits of biological materials in a public depository inherently disclosed that the inventors were in possession of the claimed sequences. *Id.* at 35. It distinguished this court's cases concerning deposits as relating to the enablement requirement of § 112, ¶ 1. *Id.* at 38-40. Enzo appealed to this court; we have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

DISCUSSION

Summary judgment is appropriate when there is no genuine issue of material fact and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c); *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-48 (1986). On motion for summary judgment, the court views the evidence and any disputed factual issues in the light most favorable to the party opposing the motion. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986). A patent is presumed to be valid, 35 U.S.C. § 282 (1994), and this presumption can only be overcome by facts supported by clear and convincing evidence to the contrary, *see, e.g.*; *WMS Gaming Inc. v. Int'l Game Techs.*, 184 F.3d 1339, 1355, 51 USPQ2d 1385, 1396-97 (Fed. Cir. 1999). "[C]ompliance with the written description requirement is a question of fact . . . ." *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563, 19 USPQ2d 1111, 1116 (Fed. Cir. 1991).

Enzo argues that its expert, Dr. Wetmer, raised a genuine factual issue that the disclosure inherently described the claimed nucleotide sequences, and that the court erred in bypassing the factual inquiry mandated by *Vas-Cath* and granting summary judgment solely on the basis of the patent's disclosure. Enzo also argues that its description of the binding affinity of the claimed nucleotide quences satisfies the requirement set forth the Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, 66 Fed. Reg. 1,099 (Jan. 5, 2001) ("*Guidelines*"). Enzo asserts that the court erred in not evaluating the patentability of the claims separately, pointing out that claims 4 and 6 are directed to the three deposited probes and variations and mixtures thereof. Enzo further asserts that the claims *per se* meet the written description requirement because they appear *in ipsis verbis* in the written description. Enzo also argues that this court's articulation of the written description requirement for genetic material in *Eli Lilly* should not apply to this case because Enzo reduced the invention to practice and deposited the derived biological materials, thereby demonstrating its "possession" of the invention.

The defendants respond that the district court properly granted summary judgment because the patent described the claimed nucleotide sequences only by their function, which is insufficient to meet the requirement of § 112, ¶ 1 as a matter of law under *Eli Lilly*, even for the narrower claims directed to the deposited materials. The defendants also assert that the expert's opinion that the deposited genetic materials could actually have been sequenced did not cure the actual failure of the inventors to identify them by some distinguishing characteristic such as their structure. The defendants argue that a description of the claimed genus of nucleotide sequences by its hybridization ratio does not satisfy § 112, ¶ 1 under this court's case law and the

Guidelines. The defendants also urge that *in ipsis verbis* support for the claims in the specification does not *per se* establish compliance with the written description requirement. Finally, the defendants assert that the district court did not err in its determination that Enzo's "possession" of three nucleotide sequences that it reduced to practice and deposited nevertheless did not satisfy the written description requirement of § 112, ¶ 1.

The written description requirement of § 112, ¶ 1 is set forth as follows:

> *The specification shall contain a written description of the invention*, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

35 U.S.C. § 112, ¶ 1 (1994) (emphasis added). We have interpreted that section as requiring a "written description" of an invention separate from enablement. *Vas-Cath*, 935 F.2d at 1563, 19 USPQ2d at 1117 (recognizing the severability of the "written description" and "enablement" provisions of § 112, ¶ 1). Compliance with the written description requirement is essentially a fact-based inquiry that will "necessarily vary depending on the nature of the invention claimed." *Id.* (citing *In re DiLeone*, 436 F.2d 1404, 1405, 168 USPQ 592, 593 (CCPA 1971)). We have also previously considered the written description requirement as applied to certain biotechnology patents, in which a gene material has only been defined by a statement of function or result and have held that such a statement did not adequately describe the claimed invention *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406. In *Eli Lilly*, we concluded that a claim to a microorganism containing a human insulin cDNA was not adequately described by a statement that the invention included human insulin cDNA. *Id.* at 1567, 43 USPQ2d at 1405. The recitation of the term human insulin cDNA conveyed no distinguishing information about the identity of the claimed DNA sequence, such as its relevant structural or physical characteristics. *Id.* We stated that an adequate written description of genetic material "'requires a precise definition, such as by structure, formula, chemical name, or physical properties,' not a mere wish or plan for obtaining the claimed chemical invention." *Id.* at 1566, 43 USPQ2d at 1404 (quoting *Fiers*, 984 F.2d at 1171, 25 USPQ2d at 1606). The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter of the claim. *Id.* at 1568, 43 USPQ2d at 1406. A description of what the genetic material does, rather than of what it is, does not suffice. *Id.*

[1] We conclude that, in this case, the district court correctly determined that the specification failed to provide an adequate written description of the claimed compositions. The court correctly found that the claimed nucleotide sequence is described only by its binding to *N. gonorrhoeae* in a preferential ratio of "greater than about five" with respect to *N. meningitidis*. While that description of the ability of the claimed probe to bind to *N. gonorrhoeae* may describe the probe's function, it does not describe the probe itself. We reject Enzo's characterization of the hybridization as a distinctive "chemical property" of the claimed sequences. The hybridization distinguishes the claimed nucleotide sequences from unclaimed sequences only by what they do, which is a purely functional distinction.

Enzo attempts to distinguish the facts of this case from those in *Eli Lilly* by asserting that its claimed probes perform a different function (hybridization) than that of the claimed sequences in *Eli Lilly* (encoding proteins), and that the former function is descriptive in the context of probes. We do not find that distinction relevant because hybridization from one DNA segment to another is just as much a functional definition as translation from a nucleic acid to a protein. As stated above, a description of genetic material by what it does — such as hybridizing to *N. gonorrhoeae* — is insufficient to satisfy § 112, ¶ 1, regardless whether the described property is labeled "chemical" or "functional." The defendants demonstrated that the claims were insufficiently described as a matter of law by the clear and convincing evidence in the patent document itself, *viz.*, the failure of the patent to describe the claimed sequences by anything other than their function. Enzo failed to raise any genuine issues of fact as to the actual description in the patent, which did not adequately characterize the claimed invention.

We also disagree with Enzo that binding affinity meets the test of an adequate description under the Guidelines. As a preliminary matter, the Guidelines, like the MPEP, are not binding on this court. *See Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1180 n.10, 33 USPQ2d 1823, 1828 n.10 (Fed. Cir. 1995) (noting that the MPEP is not binding on this court but is "entitled to judicial notice as an official interpretation of statutes or regulations as long as it is not in conflict therewith"). In any event, we do not read the Guidelines as setting forth a rule that a description of a compound by its binding affinity is sufficient to satisfy § 112, ¶ 1. Enzo points to the following statement in the Guidelines: "For some biomolecules, examples of identifying characteristics include a sequence, structure, binding affinity, binding specificity, molecular weight, and length." *Guidelines* at 1110 n.42. According to the Guidelines:

> An applicant may also show that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics which provide evidence that applicant was in possession of the claimed invention, *i.e.*, complete or partial structure, other physical and/or chemical properties, *functional characteristics when coupled with a known or disclosed correlation between function and structure*, or some combination of such characteristics.

Id. at 1106 (emphasis added); *see also* Synopsis of Application of Written Description Guidelines, at 60, *available at* http://www.uspto.gov/web/patents/guides.htm (finding compliance with § 112, ¶ 1 for a claim to "[a]n isolated antibody capable of binding to antigen X," considering "the well defined structural characteristics for the five classes of antibody, the functional characteristics of antibody binding, and the fact that the antibody technology is well developed and mature"). Enzo's claims do not meet that test. Enzo has not asserted that the claimed function is known to correlate to a specific structure or other identifying characteristic that is disclosed or is otherwise well known.

Moreover, the hybridization set out in the present claims is the only characteristic purportedly describing the claimed nucleotide sequences. The Guidelines do not provide that a nucleotide sequence may be defined only by its function. Describing a complicated molecule by means of a broad generic term (a nucleotide sequence) plus its function fails to distinguish it from other molecules that can perform the same function. A description of an anti-inflammatory steroid, *i.e.*, a steroid (a generic structural term) having the function of lessening inflammation of tissues, fails to distinguish any steroid from others having the same activity or function. Similarly, the expression "an antibiotic penicillin" fails to distinguish a particular penicillin molecule from others possessing the same activity. Thus, in the absence of sequence information for its hybridization site, a nucleic acid described only by its ability to hybridize with another DNA fails to meet the requirements of § 112, ¶ 1.

The written description requirement reflects the *quid pro quo* of our patent system, in which an inventor is only entitled to claim subject matter that is adequately described to the public. While Enzo may have deri[illegible] three nucleotide sequences that exploit so[illegible] region or regions of non-homology between *N. gonorrhoeae* and *N. meningitidis*, its broad claims are directed to all sequences that differentiate between the two strains of bacteria. The subject matter of the narrow claims (directed to the deposited probes and various permutations thereof) is similarly defined only by the function of the claimed probes, which does not identify the chemical structure of the probes themselves. In effect, Enzo made an invention of a nucleotide sequence to diagnose the presence of *N. gonorrhoeae* and claimed it in circular fashion as any nucleotide sequence that hybridizes with *N. gonorrhoeae* so as to diagnose its presence. Stated another way, Enzo claimed anything that works, without defining what works.

We are not persuaded by Enzo's arguments that the court failed to consider the separ[illegible] patentability of the claims. In its remarks, court evaluated the separate limitations of each of the claims and related those limitations to its previous *Markman* determinations. *Enzo Hearing* at 17-19. The court also clearly identified the fatal flaw in Enzo's claims: "[W]hat we have here is a definition by biological activity and function — that is, affinity of a [sic] yielding a ratio of better than five — not of its inherent structure." *Id.* at 28. That flaw is true of all of the claims, even those directed to the probes that Enzo actually made.

[2] We also conclude that Enzo's claims do not meet the written description requirement simply because they are *in ipsis verbis* supported by the specification. Even if a claim is

supported by the specification, the language of the claim must describe the invention so that one skilled in the art can recognize what is claimed. The appearance of the words of the claim in the specification or as an original claim does not necessarily satisfy that requirement. Indeed, in *Eli Lilly*, we were faced with another set of facts in which the words of the claim alone did not convey an adequate description of the invention. 119 F.3d at 1567, 43 USPQ2d at 1405. In such a situation, regardless whether the claim appears in the original specification and is thus supported by the specification as of the filing date, § 112, ¶ 1 is not met. *See Guidelines* at 1100 (noting *Eli Lilly's* repudiation of the "original claim" doctrine for situations in which the name of the claimed material does not convey sufficient identifying information). If a purported description of an invention does not meet the requirements of the statute, the fact that it appears as an original claim or in the specification does not save it. A claim does not become more descriptive by its repetition, or its longevity.

[3] Enzo also urges that it has complied with the § 112, ¶ 1 "possession" test in *Vas-Cath* by reducing its invention to practice and depositing the resulting nucleotide sequences in a public depository. We disagree. It is true that in *Vas-Cath*, we stated: "The purpose of the 'written description' requirement is broader than to merely explain how to 'make and use'; the applicant must also convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention." *Vas-Cath*, 935 F.2d at 1563-64, 19 USPQ2d at 1117. That portion of the opinion in *Vas-Cath*, however, merely states a *purpose* of the written description requirement, *viz.*, to ensure that the applicant had possession of the invention as of the desired filing date. It does not state that possession alone is always sufficient to meet that requirement. Furthermore, in *Lockwood v. American Airlines, Inc.*, we rejected Lockwood's argument that "all that is necessary to satisfy the description requirement is to show that one is 'in possession' of the invention." 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997). Rather, we clarified that the written description requirement is satisfied by the patentee's disclosure of "such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention." *Id.*

The articulation of the written description requirement in terms of "possession" is indeed useful when a patentee is claiming entitlement to an earlier filing date under 35 U.S.C. §§ 119 or 120, in interferences in which the issue is whether a count is supported by the specification of one or more of the parties, and in *ex parte* applications in which a claim at issue was filed subsequent to the application. *See Vas-Cath*, 935 F.2d at 1560, 19 USPQ2d at 1114 (describing situations in which the written description requirement may arise); *Ralston Purina Co. v. Far-Mar-Co, Inc.*, 772 F.2d 1570, 1575, 227 USPQ 177, 179 (Fed. Cir. 1985) (noting, in the context of claiming entitlement to the priority date of an earlier application, that the written description requirement is met if "the disclosure of the application relied upon reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter"). Application of the written description requirement, however, is not subsumed by the "possession" inquiry. A showing of "possession" is secondary to the *statutory mandate* that "[t]he specification shall contain a written description of the invention," and that requirement is not met if, despite a showing of possession, the specification does not adequately describe the claimed invention. After all, one can show possession of an invention by means of an affidavit or declaration during prosecution, as one does in an interference or when one files an affidavit under 37 C.F.R. § 1.131 to antedate a reference. However, such a showing of possession does not substitute for a written description in the specification, as required by statute.

The written description requirement is the most basic requirement of the patent law — to adequately identify what one has invented. It is true that knowledge of one skilled in the art is relevant to meeting that requirement, as it is to enablement. An invention may be properly enabled even if some experimentation is required to practice it, provided that experimentation is not undue. However, to require the public to go to a public depository and perform experiments to identify an invention is not consistent with the statutory requirement to describe one's invention in the specification.

Enzo's "possession" of the invention does not contribute to its description in the patent specification. True, Enzo apparently has achieved more than a "wish" or a "plan" for obtaining the claimed genetic material. However, its mere possession of three nucleotide sequences that are within the scope of the claims does not provide sufficient distinguishing information about those sequences for purposes of satisfying § 112, ¶ 1. Enzo provided only vague details about the nucleotide sequences: how they were obtained (but not meaningfully identified) and their approximate lengths. '659 patent, col. 13, ll. 26-60; col. 26, l. 56 to col. 27, l. 20. That meager information does not allow one skilled in the art to visualize or recognize the identity of the claimed subject matter.

[4] Moreover, we disagree with Enzo that biological deposits necessarily satisfy the written description requirement. In *Lundak*, we clarified that the "deposit requirement applies only to biological materials that are not readily reproducible from their written description" and reversed a rejection by the Board for failure to meet the *enablement* requirement by a post-filing date deposit. *In re Lundak*, 773 F.2d 1216, 1217, 227 USPQ 90, 92 (Fed. Cir. 1985). We also reversed the Board's holding that the post-filing date deposit violated the prohibition against new matter in 35 U.S.C. § 132. *Id.* at 1223, 227 USPQ at 95. We stated that: "An accession number and deposit date add nothing to the written description of the invention. They do not enlarge or limit the disclosure." *Id.* at 1123, 227 USPQ at 96. *Lundak* thus supports our conclusion that Enzo's disclosure that it deposited embodiments of the invention does not *ipso facto* describe that invention.

There are other reasons why a public deposit does not substitute for a description of an invention in the specification. An adequate description is necessary for proper examination of an application. *Lundak*, 773 F.2d at 1223, 227 USPQ at 95 ("The examination for patentability proceeds solely on the basis of the written description."); *Guidelines* at 1107-08 n.6 ("The written description of the deposited material needs to be as complete as possible because the examination for patentability proceeds solely on the basis of the written description."). Furthermore, the Guidelines state that " '[o]nce the patent issues, the description must be sufficient to aid in the resolution of questions of infringement.' " *Guidelines* at 1107-08 n.6 (quoting Deposit of Biological Materials for Patent Purposes, Final Rule, 54 Fed. Reg. 34,864, 34880 (Aug. 22, 1989) (codified at 37 C.F.R. pt. 800)).

We therefore conclude that "a deposit is not a substitute for a written description of the claimed invention." *Guidelines* at 1107-08 n.6. Even if Enzo's expert, Dr. Wetmur, were correct that one of skill in the art could routinely sequence the deposited material and so obtain a description of those deposits, that description is not in the patent. The written description requirement is not satisfied by what could have been disclosed, but was not. *See Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966 (stating that the description requirement is not met by combining the actual disclosure with knowledge in the art).

[5] Finally, Enzo asserts that a reduction to practice is sufficient to satisfy the written description requirement under the Guidelines. Specifically, the Guidelines provide examiners with a methodology for determining the adequacy of the written description. The Guidelines read as follows:

> Description of an actual reduction to practice offers an important "safe haven" that applies to all applications and is just one of several ways by which an applicant may demonstrate possession of the claimed invention. Actual reduction to practice may be crucial in the relatively rare instances where the level of knowledge and level of skill are such that those of skill in the art cannot describe a composition structurally, or specify a process of making a composition by naming components and combining steps, in such a way as to distinguish the composition with particularity from all others. Thus, the emphasis on actual reduction to practice is appropriate in those cases where the inventor cannot provide an adequate description of what the composition is, and a definition by function is insufficient to define a composition "because it is only an indication of what the [composition] does, rather than what it is." *Eli Lilly*, 119 F.3d at 1568, 43 USPQ at 1406.

Id. at 1101. This is not a case in which the inventors could not have provided a description of the nucleotide sequences. Moreover, we do not purport to indicate how the Guidelines ap-

ply to cases not before us. Although an actual reduction to practice, assuming one exists here, may demonstrate possession of an embodiment of an invention, it does not necessarily describe what the claimed invention is. In the context of this case, the disclosure of the way the invention was reduced to practice does not satisfy the more fundamental written description requirement set forth in the statute: "[t]he specification shall contain a written description . . . ." Enzo has merely disclosed that it obtained the sequences, but it has not identified them. We therefore conclude that Enzo's description of its reduction to practice, unaccompanied by any written disclosure of meaningful, distinguishing characteristics of the claimed invention, does not satisfy the written description requirement of § 112, ¶ 1.

A few comments are in order relating to the dissent. Although determination whether the written description requirement has been met raises factual issues, no fact-finding is needed to determine, as the trial court did, that the claimed nucleotide sequences are identified here only by their function. Such an omission renders the application legally deficient in terms of satisfying the written description requirement.

The dissent indicates that the degree of hybridization between a probe and a bacterial target depends on the degree of complementarity between the structures of the probe and the bacterium. That is true, but, failing a description of the sequence of a bacterium in the specification, including the specific point on the sequence that binds to the probe, there is no written description of the claimed invention in the specification. The specification acknowledges that the sequences of the bacteria were not determined. '659 patent, col. 3, ll. 39-46.

The dissent states that deposit of a sample of the invention in a recognized depository "is an ideal way" of satisfying the written description requirement. We do not agree. Deposits originated as a means of enabling practice of the invention when a unique starting material is required to practice it. Without a description of what the invention is, however, the notice function of a description in the patent has still not been satisfied. What the deposit does, in addition to enabling the practice of the invention, is tell the public where a sample of the invention can be found so that the invention can be carried out when the patent expires or used in other ways that may not infringe the patent. That is not describing the invention in the patent. The dissent notes that it is ironic that we do not question the use of the depository to describe the object of the invention. That is not the purpose of a depository. A depository is not part of a patent specification. It exists to provide samples of microorganisms, for patent purposes and otherwise.

The dissent indicates that the PTO found the reference to the deposited materials to be sufficient. While it is true that the PTO did not make a written description rejection relating to the deposit, it is also clear that its objection concerning the deposit, which was later satisfied, related to enablement, which has traditionally been the purpose of a deposit. Here, in contrast to the use of a microorganism to make another invention, which raises the enablement issue, the deposit here essentially contains the invention, and the invention must be described more than by stating that it exists in a depository.

CONCLUSION

For the foregoing reasons, we conclude that the district court did not err in granting summary judgment that the claims of the '659 patent are invalid for failure to meet the written description requirement of § 112, ¶ 1. The district court clearly understood the governing case law and Enzo's patent specification.

AFFIRMED

Dyk, J., dissenting.

This case presents two significant issues relating to the written description requirement —one old and one new. I respectfully dissent from the majority's decision on each of these issues and its decision to hold the claims of U.S. Patent No. 4,900,659 (the "'659 patent") invalid.

First, the majority, like the district court, holds that all claims fail to satisfy the written description requirement as a matter of law. It is well established that the written description requirement presents a factual issue. Our established precedent requires a determination whether one skilled in the art at the time the application was filed would understand the nature of the claimed invention from the written description. No adequate record for summary judgment has been made in this case on that issue, much less a record that establishes invalidity by clear and convincing evidence as a matter of law. Second, with respect to claims 4 and 6 the majority holds that a deposit in the American Type Culture Collection ("ATCC") cannot be used to satisfy the written description requirement. This is a matter of first impression, but I suggest that the majority's decision is both incorrect and unfortunate from the perspective of sound public policy.

1. *All Claims*

Claim 1 essentially claims nucleotide sequences which selectively hybridize to the DNA of *N. gonorrhoeae* as opposed to hybridizing to the DNA of *N. meningitidis*. Claim 5 essentially claims a method of detecting *N. gonorrhoeae* by using the nucleotide sequence of claim 1 as a probe. Claims 1 and 5 may be characterized as genus claims, as the claimed nucleotide sequence is not limited to a particular species. The other claims of the patent (claims 2, 3, 4, and 6) depend from either claim 1 or 5. The specification discloses, in great detail, the implementation of well-known screening methods for isolating the claimed nucleotide sequences. '659 Patent, col. 4, l. 46 – col. 12, l. 65. Two embodiments of the claimed nucleotide sequences are described as having about 850 base pairs and one other embodiment is described as having about 1300 base pairs. The claimed sequences are defined by their selective hybridization to the DNA of six specifically identified strains of *N. gonorrhoeae* which are on deposit with the ATCC as opposed to hybridizing to the DNA of six specifically identified strains of *N. meningitides* on deposit with the ATCC.

The defendant-appellees sought to invalidate the claims of the patent for failure to satisfy the written description requirement. When moving for summary judgment on the issue of invalidity, they did not rely on any testimony from anyone of ordinary skill in the art.[1] They relied purely on attorney argument to support their claim as to why the claims do not satisfy the written description requirement. The district court held as a matter of law based on its own examination of the text of the patent that the patent was invalid for failure to satisfy the written description requirement. The majority agrees with the defendants' argument that the specification "is insufficient to meet the requirement of § 112, ¶ 1 as a *matter of law* . . . ." *Ante* at 5.

We have repeatedly held, including in *Eli Lilly*, that "[w]hether a specification complies with the written description requirement of § 112, ¶ 1, is a question of fact . . . ." *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1566, 43 USPQ2d 1398, 1404 (Fed. Cir. 1997), *cert. denied* 523 U.S. 1089 (1998). Moreover, the sufficiency of the description is measured from the point of view of one of ordinary skill in the art as of the time the description is filed. *Reiffin v. Microsoft Corp.*, 214 F.3d 1342, 1346, 54 USPQ2d 1915, 1917-18 (Fed. Cir. 2000). In *In re Alton*, 76 F.3d 1168, 1174-75, 37 USPQ2d 1578, 1583-84 (Fed. Cir. 1996), this court reversed a decision of the Patent and Trademark Office ("PTO") Board of Patent Appeals and Interferences ("Board") upholding an examiner's rejection of Alton's patent application for failure to comply with the written description requirement. Alton had submitted a declaration from one of ordinary skill in the art stating that one of ordinary skill in the art would have understood the specification as adequately describing the claimed invention. *Id.* at 1172-73, 37 USPQ2d at 1581-82. The examiner gave little or no weight to this declaration, contending that it was "an opinion affadavit on the ultimate legal question at issue." *Id.* at 1174, 37 USPQ2d at 1583. We reversed because the examiner and the Board applied the wrong legal standard by viewing the declaration as addressing a question of law rather than a question of fact, and required the PTO to evaluate the expert's affadavit as bearing on the factual issue. *Id.*

The majority here finds support for its approach in *Eli Lilly*. *Eli Lilly*, in departing from the general rule that an applicant satisfies the written description requirement by "convey[ing] with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention," *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991), and imposing a unique written description requirement in the field of biotechnology, is open to serious question. But even *Eli Lilly* does not sanction the approach taken here. *Eli Lilly* recognized, of course, that there are situations in which the written description is so deficient that it fails to satisfy the written

[1] Appellees apparently submitted a declaration from Dr. Philip Sparling, but concede here that they did not rely on this declaration when moving for summary judgment.

description requirement as a matter of law. In *Eli Lilly* itself the patent claimed "2. [a] recombinant procaryotic microorganism modified to contain a nucleotide sequence having the structure of the reverse transcript of an mRNA of a vertebrate, which mRNA encodes insulin," U.S. Patent No. 4,652,525, col. 21, ll. 1-5, and "5. [a] microorganism according to claim 2 wherein the vertebrate is a human." *Id.* at col. 22, ll. 3-4. The claimed "reverse transcript of an mRNA [also known as "cDNA"] of a vertebrate" was not described by sequencing. Instead, the patent simply named the cDNA and described the process that could be used for isolating it. We held:

> The name cDNA is not itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA. Describing a method of preparing a cDNA or even describing the protein that the cDNA encodes, as the example does, does not necessarily describe the cDNA itself. No sequence information indicating which nucleotides constitute human cDNA appears in the patent, as appears for rat cDNA in Example 5 of the patent. Accordingly, the specification does not provide a written description of the invention of claim 5.

Eli Lilly, 119 F.3d at 1567, 43 USPQ2d at 1405.

The patent here is quite different. It states that the claimed nucleotide sequences specifically hybridize to the DNA of particular strains of *N. gonorrhoeae* on deposit with the ATCC and not to the DNA of particular strains of *N. meningitidis* on deposit with the ATCC. The parties agree that this selective hybridization of the claimed sequences is indicative of a structure that is more complementary to the structures of the DNAs of the disclosed *N. gonorrhoeae* strains than to those of the *N. meningitidis* strains. As the majority correctly points out "Enzo may have derived three nucleotide sequences that exploit some region or regions of non-homology between *N. gonorrhoeae* and *N. meningitidis* . . . ." *Ante* at 10. The majority discounts this description as merely functional, *ante* at 8, 10, but I view the description as identifying a structural difference between the DNAs of *N. gonorrhoeae* and *N. meningitidis*. The property of the claimed nucleotide sequences hybridizing to particular, known DNAs is a direct result of the structure of the nucleotide sequence. The degree of hybridization between a probe and a target depends on the degree of complementarity between the chemical structure between the probe and the target. To be sure, the sequences and the chemical structure of the targets were not disclosed in the specification, but the targets were not novel, and the "Background" section of the patent states that the degree of homology between the *N. gonorrhoeae* and *N. meningitidis* DNA targets was known to be between 80% to 93%. '659 patent, col. 2, ll. 61-64. This indicates that the structure of the targets was at least somewhat known to those of skill in the art. Thus, by describing the degree of hybridization of the claimed nucleotide sequences, the specification may adequately describe the structure of the claimed sequences. At least one of ordinary skill in the art might so conclude. There has been no factual showing that one of skill in the art would not understand that the claimed invention is described by a written description of its hybridization-specific properties.[2]

In light of the appellees' failure to make a factual showing supporting summary judgment, we should reverse the district court's summary judgment of invalidity and remand to the district court for a factual finding, after a hearing, of whether one of ordinary skill in the art would consider the specification to describe the claimed invention.

2. *Claims 4 and 6.*

Claims 4 and 6, which depend from claims 1 and 5, respectively, provide an even more

[2] The majority faults the specification for failing to describe the amino acid sequences of the targets, and points out that the patent itself acknowledges that the sequences of the targets were not determined. *Ante* at 17. But the patent states the reason the sequences were not determined is because at the time of the filing of the application in 1986 "it would [have] take[n] 3,000 scientists one month to sequence the genome of one strain of *Neisseria gonorrhoeae* and one strain of *Neisseria meningitidis*." '659 patent, col. 3, ll. 43-46. I do not believe that the patent laws require such a Herculean effort on the part of the patentee when one of ordinary skill in the art might understand the nature of his invention from a simpler written description of it.

detailed written description. They are directed to the nucleotide sequences of particular deposited samples, deposited with the ATCC. The samples are identified by their deposition numbers, ATCC 53409, ATCC 53410, ATCC 53411, and were deposited on January 9, 1986, twenty-one days before the patent application was filed. '659 patent, col. 13, ll. 9-13.

Claim 4 depends from claim 1, and further limits claim 1 to "nucleotide sequences . . . selected from the group *consisting of*: (a.) the *Neisseria gonorroheae* DNA insert of ATCC 53409, ATCC 53410 and ATCC 53411, and discrete nucleotide subsequences thereof, (b.) mutated discrete nucleotide sequences of any of the foregoing inserts that are within said hybridization ratio and subsequences thereof; and (c.) mixtures thereof." '659 patent, col. 28, ll. 33-39 (first emphasis added).

Claim 6 depends from claim 5, and further limits claim 5 to a screening method using a polynucleotide probe in which the "polynucleotide probe is a composition selected from the group *consisting of* the *Neisseria gonorrhoeae* DNA insert of ATCC 53409, ATCC 53410 and ATCC 53411, and discrete nucleotide subsequences thereof; and mutated discrete nucleotide subsequences of any of the foregoing inserts . . . ." '659 Patent, col. 28, ll. 47-52 (first emphasis added).

On the face of it, a specification that describes the invention by reference to a deposit of a sample of the invention in a recognized depository is an ideal way of satisfying the written description requirement. The primary purpose of the statutory written description requirement is to provide notice to competitors and the public of the scope of the patent claims. The Supreme Court has stated that

> The object of the statute is to require the patentee to describe his invention so that others may construct and use it after the expiration of the patent and "to inform the public during the life of the patent of the limits of the monopoly asserted, so that it may be known which features may be safely used or manufactured without a license and which may not."

Schriber-Schroth Co. v. Cleveland Trust Co., 305 U.S. 47, 57 (1938) (quoting *Permutit Co. v. Graver Corp.*, 284 U.S. 52, 60 (1931)). Our predecessor court stated that "the 'essential goal' of the description of the invention requirement is to clearly convey the information that an applicant has invented the subject matter which is claimed." *In re Barker*, 559 F.2d 588, 592 n.4, 194 USPQ 470, 473 n.4 (CCPA 1977), *cert. denied* 434 U.S. 1064 (1978). A description by reference to the deposited sample provides a precise and unmistakably clear description of the invention that is accessible to the public.

However, the majority correctly points out that the written description requirement has a second purpose — to enable the PTO to conduct an examination of the patent application. The majority holds that reference to the deposited samples in claims 4 and 6 does not satisfy the written description requirement of 35 U.S.C. § 112 because "[a]n adequate description is necessary for proper examination of an application" and "[t]he examination of the application for patentability proceeds solely on the basis of the written description." *Ante* at 14. The majority concludes that "a deposit is not a substitute for a written description." *Ante* at 15. I think that reference to deposits is sufficient for proper examination of applications.

First, in the context of biotechnology inventions, the PTO has adopted regulations governing the deposit of biological materials. 37 C.F.R §§ 1.801 – 1.809. Those regulations provide *inter alia* that "[w]here an invention is, or relies on, a biological material, the disclosure may include reference to a deposit of such biological material." 37 C.F.R. § 1.802(a) (2001). Section 1.803 establishes criteria a depository must meet in order to be acceptable for the purposes of the PTO. When a deposit is made in an acceptable depository, "*[t]he examiner shall determine* . . . if a deposit is needed, and if needed, *if a deposit actually made is acceptable for patent purposes.*" 37 C.F.R. § 1.809(a) (2001) (emphases added). The regulations merely require that the specification contain "[a] description of the deposited biological material sufficient to specifically identify it and to permit examination." 37 C.F.R. § 1.809(d)(3)(2001). When adopting § 1.809(d)(3), the PTO specifically rejected a suggestion that would have required an application to contain a specification that would "fully identify and describe the deposited material." Deposit of Biological Materials for Patent Purposes, 54 Fed. Reg. 34,864, 34,874 (Aug. 22, 1989). In short, the PTO has made clear that applicants may take advantage of a biological depository, and contemplates that deposited material may be used for writ-

ten description purposes. There is no necessity that the PTO actually examine the cell deposits when determining that the patent satisfies the written description requirement.

Second, the examiner did not here find the written description inadequate for examination purposes. If the examiner here had rejected the application for failure to satisfy the written description requirement and had insisted on a written description that set forth the gene sequencing, on an appeal from the Board we would have quite a different question. But the possibility that the PTO could require something more in the way of a written description should not cause us to reject cell deposits as satisfying the written description requirement when the PTO has concluded, as here, that the cell deposit is sufficient for written description purposes and the PTO's own examination.

In the examiner's first Office action the examiner recognized the importance of the deposited materials and required the applicant to assure public access to the microorganisms. The examiner stated:

> The specification is objected to under 35 U.S.C. 112, first paragraph, as failing to provide an enabling disclosure.
>
> Applicants are required to assure public access to the deposited microorganisms. The requirements are: The duration of the deposit be for 30 years from the date of deposit or for 5 years after the last request for the deposit at the depository or for the enforceable life of the U.S. patent whichever is longest. Also all of the other requirements of MPEP 608-01(p) Section C are in effect. It is also required that the organisms will be replenished should they become non-viable.
>
> Claims 1-8 are rejected under 35 U.S.C. 112, first paragraph, for the reasons set forth in the above objection to the specification.

The patentee did what the examiner required. In this Office action, the examiner rejected the claims under 35 U.S.C. § 112 for failing to provide an enabling disclosure. However, the examiner did *not* reject the claims for failure to comply with the written description requirement and eventually approved the application. And the examiner specifically addressed the applicant's use of the depository, but did not object to the application on written description grounds. The PTO's acceptance of the adequacy of the written description here reflects a determination by the PTO, pursuant to 37 C.F.R. § 1.809, that the deposited material was "acceptable for patent purposes," including compliance with the written description requirement and that review of the deposit and a description in the specification by sequencing was unnecessary for PTO examination. Nevertheless, the majority invalidates all claims of the patent on the same record that the PTO had before it.

The consequence of the majority's approach, I think, is considerable unfairness to an applicant which, finding no statutory or regulatory bar to reliance on a cell deposit for written description purposes, and finding that the PTO itself is satisfied with reliance on a cell deposit, secures a patent that relies on a cell deposit only to have this court conclude after the fact that this reliance is impermissible. At this point it is far too late to amend the application, which was deemed satisfactory by the PTO. If the cell deposit were inadequate for public notice purposes, the majority's approach would be quite appropriate. But where the only purpose served by our insistence on a better written description is to enable the PTO's own examination, and the PTO itself was satisfied, we should not be second-guessing the PTO's own judgment. *Cf. Dethmers Mfg. Co. v. Automatic Equip. Mfg. Co.*, 272 F.3d 1365, 1379, 60 USPQ2d 1929, 1939 (Fed. Cir. 2001) (Dyk, J., dissenting) ("[W]e are obligated by clear Supreme Court precedent to give deference to the PTO's own interpretation of its regulations.").

The practical effect of the majority's holding that reference to the depository is insufficient to satisfy the written description requirement is to make description by reference to the depository impossible. This is quite inconsistent with the statutory and regulatory scheme.[3]

For these reasons, I respectfully dissent.

[3] Ironically, the majority raises no question about the use of the ATCC depository to describe the object of the invention – to create a probe that specifically hybridizes to known strains of *N. gonorrhoeae* on deposit with the ATCC and not to particular strains of *N. meningitidis* on deposit with the ATCC.

Estate of Burne Hogarth v. Edgar Rice Burroughs Inc.

U.S. District Court
Southern District of New York
No. 00 CIV. 9569 (DLC)
Decided March 15, 2002

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[1] Rights in copyright; infringement — Ownership of copyright — Works made for hire (§ 213.0305)

Infringement defendant has established that "Tarzan" books created by well-known illustrator are works made for hire under "instance and expense" test, even though illustrator was independent contractor rather than employee, since record shows that creation of books was first "instanced" by defendant corporation's vice president, that illustrator would not have undertaken production of artwork for books without receiving assignment from defendant, and that vice-president closely supervised creation of books, and since books were produced at defendant's expense through its payment of non-refundable advance against royalties to illustrator, salaried work of its executive, its full assumption of risk of loss on project, and other obligations; illustrator's royalty participation, his work on books in his own studio with his own materials, and his payment of certain costs that he was not contractually bound to pay do not require contrary result.

[2] Rights in copyright; infringement — Ownership of copyright — Works made for hire (§ 213.0305)

Plaintiffs have failed to rebut presumption, established by infringement defendant, that "Tarzan" books created by well-known illustrator are works made for hire under "instance and expense" test, since lengthy introductions in books praising illustrator's artistry, and dedication of books to illustrator's parents, do not establish that illustrator was legal author, since agreement between illustrator and defendant contains indicia of work-for-hire contract, and parties did not question that defendant had ultimate control over illustrator's work, and since agreement grants defendant copyright in illustrator's work, but makes no guarantee that it will publish his work regardless of acceptability of final product; although plaintiffs argue that agreement did not give defendant control over illustrator's every pen stroke, work-for-hire presumption is not rebutted by showing that proprietor's degree of control did not extend to every aspect of independent contractor's work.

[3] Rights in copyright; infringement — Ownership of copyright — Works made for hire (§ 213.0305)

Illustrator's conveyance of rights in books at issue, in agreement between illustrator and infringement defendant made under Copyright Act of 1909, does not rebut presumption that "Tarzan" books created by illustrator are works made for hire under "instance and expense" test, since 1909 Act only governed works after they were published, and left their protection before publication to common law copyright, since there is strong evidence to show that defendant included "conveyance" passage in agreement merely to protect its rights as hiring party before publication, rather than as recognition that illustrator had reserved copyright in his work, and since agreement specifically refers to defendant as "proprietor" of books.

[4] Notice, deposit, and registration — Registration — Effect (§ 207.0702)

Rights in copyright; infringement — Ownership of copyright — Works made for hire (§ 213.0305)

JUDICIAL PRACTICE AND PROCEDURE

Procedure — Limitations period; timeliness (§ 410.05)

Copyright infringement defendant is not time-barred from asserting work-for-hire authorship of books at issue due to its failure to correct copyright registrations for books which list well-known illustrator, rather than defendant, as author, since facts alleged in copyright registrations do not become incontestable after certain period of time, since defendant and illustrator both acted at all relevant times as if defendant was "author" of books for purposes of copyright ownership, and since first "injury" to defendant occurred only recently, when plaintiffs, who are illus-